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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,207	01/08/2001	Michael Stuke	HUBR1165 100	5279
24972	7590	03/04/2004	EXAMINER	
FULBRIGHT & JAWORSKI, LLP			ROSSI, JESSICA	
666 FIFTH AVE			ART UNIT	PAPER NUMBER
NEW YORK, NY 10103-3198			1733	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/647,207	STUKE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Jessica L. Rossi	1733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11/14/03, Amendment.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 23,24,26-34,36,37 and 45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 23,24,26-34,36,37 and 45 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. This action is in response to the amendment dated 11/14/03. Claims 25, 35, and 38-39 were canceled. Claims 23-24, 26-34, 36-37, and 45 are pending.
2. The rejection of claims 23-29, 31-39, and 45 under 35 U.S.C. 103(a) as being unpatentable over McReynolds in view of Soane et al. and optionally in view of Dixon et al., as set forth in paragraph 9 of the previous office action, has been withdrawn in light of Applicants' arguments pertaining to the Dixon reference.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 37, it is unclear what Applicants mean by the holding temperature being within +/- 3°C of the heating temperature. According to claim 1, the substrate and cover are heated to the heating temperature and then held at that temperature, so how can the heating temperature and holding temperature differ? Applicants are asked to clarify.

### ***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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6. Claims 23-24, 26-29, 31-34, 36-37, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al. (US 6176962; of record) in view of McReynolds (US 5882465; of record) and Oshida et al. (US 3997386; provided in IDS).

With respect to claim 23, Soane is directed to adhesive-free bonding (column 5, lines 21-23) of microfluidic devices. The reference teaches preparing a polymeric substrate 12, which has depressions forming microchannels 21 and 23, and applying a polymeric cover 14 to the substrate by uniform pressure (Figures 5-6; column 2, lines 39-46 and 58-65). The reference teaches heating the substrate and cover to 2-5°C above the glass transition temperature of the substrate and cover, while still applying pressure to the cover, and holding them at this temperature (column 2, line 63 – column 3, line 4). Soane teaches slowly reducing/cooling the temperature of the substrate but fails to disclose any specifics pertaining to this cooling step (column 3, lines 6-9). Soane is also silent as to Applicants' claimed pressure range and holding the substrate and cover at the elevated temperature for at least 15 minutes.

It is known in the art to produce microfluidic devices using an adhesive-free bonding process, where a polymeric substrate having microchannels is bonded to a polymeric cover by the application of heat and pressure, as taught by McReynolds (column 3, lines 15-19 and 40-43; column 4, lines 24-26 and 33-36). McReynolds acknowledges that the applied temperature and pressure will depend on the nature of the polymeric material (column 4, lines 33-36); it being noted that McReynolds (column 3, lines 41-43) discloses polymers (i.e. polymethyl methacrylate) identical to those of the present invention (claim 45) and Soane (column 9, line 66 – column 10, line 1).

Therefore, selection of a particular pressure range for the process of Soane would have been within purview of the skilled artisan at the time the invention was made depending on the polymeric material used because such is known in the art, as taught by McReynolds, wherein the skilled artisan would have been inclined to select a pressure range that produced a strong bond without deforming the substrate and/or cover.

As for holding the substrate and cover of Soane at the elevated temperature for a specific period of time, it is noted that Soane specifically points out that the temperature is held “**for a time period sufficient** to allow the polymer molecules to interpenetrate the polymeric surfaces of the substrate and cover and create a morphological bonding” (column 3, lines 1-4). The skilled artisan reading the reference as a whole would have readily appreciated that selection of such a time period would have been determined by the polymeric materials used, such that the polymer molecules have sufficient time to interpenetrate the surfaces of the substrate and cover in order to create a satisfactory bond; it being noted that Soane teaches polymeric materials (i.e. polymethyl methacrylate; column 9, line 67 – column 10, line 1) identical to those of the claimed invention (see claim 45).

It is known in the art to bond two polymeric substrates made from the same or different thermoplastic materials (i.e. polymethyl methacrylate; see Table in column 3) using an adhesive-free bonding process wherein the substrates are pressed together while heating them to a temperature above their glass transition temperatures, as taught by Oshida (abstract; column 1, lines 6-8; column 1, line 30 – column 2, line 5). The substrates are then subjected to “slow cooling,” which the reference defines as a cooling speed of about 5°C/sec, wherein the adjective “slow” refers to the number of degrees the temperature of the substrates is reduced/cooled per

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unit time and NOT the total amount of time that cooling takes place (column 2, lines 33-36). In the examples, the reference teaches heating to 110°C (23°C above a glass transition temperature of 87°C) and then cooling to 55°C at a 5°C/sec cooling speed (column 3, lines 25-27); therefore, the skilled artisan would have appreciated that the substrates are cooled for about 11 sec.

The examiner would like to point out that Oshida teaches the substrates undergoing further “natural cooling” upon exposure to room temperature after “slow cooling” has taken place (column 3, lines 28-30); however, the examiner would also like to point out that the present invention teaches “cooling up to 30 seconds” taking place within a cabinet in which the device was heated and then removing the cooled device from the cabinet (p. 4, lines 13-15; p. 5, lines 5-8), wherein the skilled artisan would have appreciated that like the device of Oshida, the device of Soane would also undergo “natural cooling” when removed from the cabinet since it would be exposed to room temperature.

Therefore, it would have been obvious to the skilled artisan at the time of the invention to slowly reduce the temperature of the substrate of Soane using a cooling speed of 5°C/sec such that cooling takes place for up to 30 seconds because such is known in the art, as taught by Oshida, and it avoids overcooling (Oshida; column 2, lines 34-36).

Regarding claims 24, 29, and 45, Soane teaches using polymethyl methacrylate for the substrate and cover (column 9, line 67 – column 10, line 1).

Regarding claims 26-28, Soane teaches the depressions being 50-750 µm (column 1, lines 35-43).

Regarding claims 31-32, Applicants are directed to the rejection of claim 23 set forth above.

Regarding claims 33 and 36, Applicants are directed to the rejection of claim 23 set forth above.

Regarding claims 34 and 37, Applicants are directed to the rejection of claim 23 set forth above.

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al., McReynolds, and Oshida et al. as applied to claim 23 above, and further in view of Parce et al. (US 6046056; of record).

Regarding claim 30, Soane is silent as to at least the cover being transparent. It would have been obvious to the skilled artisan at the time the invention was made to use a transparent polymeric cover and/or substrate for those of Soane because such is known in the microfluidic device art, as taught by Parce (column 8, lines 57-66; column 9, lines 7-15), and this enables the microfluidic device to include a visual detection element (Parce; column 8, line 65 – column 9, line 3).

#### ***Response to Arguments***

8. Applicant's arguments filed 11/14/03 have been fully considered but they are not persuasive.

9. On page 5 of the arguments, Applicants argue that Soane teaches away from rapid cooling since the reference states that the temperature of the substrate and cover is slowly reduced.

As set forth above in paragraph 6, the examiner applied the Oshida reference to show that reducing the temperature of substrates that have been thermally bonded by heating them to a temperature above their glass transition temperatures involves a “slow cooling” process where

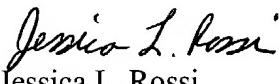
cooling takes place for a period of time (i.e. 11 seconds) consistent with Applicants' claimed range (up to 30 seconds). Use of the word "slow" is somewhat misleading, but reading the Oshida reference as a whole allows the skilled artisan to appreciate that this adjective is being used to describe the number of degrees the temperature of the substrates is reduced/cooled per unit time and NOT the total amount of time that cooling takes place.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jessica L. Rossi** whose telephone number is **571-272-1223**. The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard D. Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jessica L. Rossi  
Patent Examiner  
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